September 26, 2003 U.S.S.N. 09/776,250 (1225/1G584US2)

REVISIONS TO DRAFT OF EXAMINER'S AMENDMENT PER 9/23/2003 INTERVIEW

1. "Mark-Up"

1-20. (Cancelled)

21. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a first composition comprising 2×10^5 to about 2.5×10^6 haptenized or non-haptenized autologous tumor cells or tumor cell equivalents free ~~or~~ of any adjuvant;

(b) ~~four to seven days after the initiation of the treatment,~~ an immunomodulatory agent that inhibits immune suppression; and

(c) at least one additional composition comprising from about ~~1×10^6 to 2.5×10^6~~ 2×10^5 to 1×10^7 autologous tumor cells or tumor cell equivalents, wherein said tumor cell or tumor cell equivalents are conjugated to a hapten.

22. The method of claim 21, in which the immunomodulatory compound is cyclophosphamide.

23. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a composition comprising 2×10^5 to 2.5×10^6 haptenized or non-haptenized autologous tumor cells or tumor cell equivalents free ~~or~~ of any adjuvant;

(b) four to seven days after initiation of the treatment, cyclophosphamide; and

(c) at least one week after initiation of the treatment, a composition comprising an adjuvant and from 2×10^5 to about 1×10^7 autologous tumor cells or tumor cell equivalents, wherein said tumor ~~cell~~ cells or tumor cell equivalents are conjugated to a hapten.

24. The method in claim 23, in which the adjuvant is *Bacille Calmette-Guerin*.

25. The method of claim 21, wherein the composition administered on the first day of treatment comprises haptenized tumor cells or tumor cell equivalents.

26. The method of claim 21, wherein the composition administered on the first day of treatment comprises a mixture of haptenized and non-haptenized tumor cells or tumor cell equivalents.

27. (Cancelled)

28. (Revised) The method of claim ~~26~~ 21, wherein the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.

29. The method of claim 28, in which the hapten is dinitrophenyl.

30. (Revised) The method of claim 21, wherein the composition administered on the first day of treatment ~~comprise~~ comprises tumor cell equivalents.

31. (Cancelled)

32. The method of claim 21, wherein the tumor cells or tumor cell equivalents originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.

33. The method of clam 21, wherein the tumor is melanoma.

34. The method of claim 21, wherein the tumor is ovarian cancer.

35. The method of claim 21, wherein the tumor cells are rendered incapable of growth or multiplication *in vivo* by irradiation.

36. (Cancelled)

37. The method of claim 21, wherein the tumor cells of the first composition are rendered incapable of growth or multiplication *in vivo* by haptenization.

38. The method of claim 23, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

39. The method of claim 21, wherein the mammalian patient is a domestic pet or livestock.

40. The method of claim 21, wherein the immunomodulatory agent is administered 5 to 7 days after initiation of the treatment.

41. The method of claim 21, wherein the patient is a human.

42. The method of claim 23, wherein the mammalian patient is a domestic pet or livestock.

43. (Revised) The method of claim ~~23~~ 21, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

44. The method of claim 23, wherein the patient is a human.

45. The method of claim 23, wherein the cyclophosphamide is administered 5 to 7 days after initiation of the treatment.

46. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a first composition comprising 2×10^5 to about 2.5×10^6 haptenized or non-haptenized tumor cells or tumor cell equivalents free of any adjuvant;

(b) ~~four to seven days after the initiation of the treatment,~~ an immunomodulatory agent that inhibits immune suppression; and

(c) at least one additional composition comprising from about 2×10^5 to 1×10^7 tumor cells or tumor cell equivalents, wherein said tumor cell or tumor cell equivalents are conjugated to a hapten.

47. (Revised) The method of claim ~~46~~ 23, wherein the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.

48. The method of claim ~~46~~ 23, wherein the tumor is melanoma.

49. The method of claim ~~46~~ 23, wherein the tumor is ovarian cancer.

50. (Revised) The method of claim 46, wherein the second composition comprises an adjuvant ~~is~~ selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

51-54. (Cancelled)

55. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a composition comprising 2×10^6 to 2.5×10^6 haptenized or non-haptenized ~~autologous~~ tumor cells or tumor cell equivalents free ~~or~~ of any adjuvant;

(b) four to seven days after initiation of the treatment, cyclophosphamide; and

(c) at least one week after initiation of the treatment, a composition comprising an adjuvant and from 2×10^5 to 1×10^7 ~~autologous~~ tumor cells or tumor cell equivalents, wherein said tumor ~~cell~~ cells or tumor cell equivalents are conjugated to a hapten.

56. (Revised) The method ~~in~~ of claim 55, in which the adjuvant is *Bacille Calmette-Guerin*.

57. (Added) The method of claim 23, wherein the tumor cells or tumor cell equivalents originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.

2. "Version Showing Changes Made"

21. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a first composition comprising 2×10^5 to about 2.5×10^6 haptenized or non-haptenized autologous tumor cells or tumor cell equivalents free of any adjuvant;

(b) an immunomodulatory agent that inhibits immune suppression; and

(c) at least one additional composition comprising from about 2×10^5 to 1×10^7 autologous tumor cells or tumor cell equivalents, wherein said tumor cell or tumor cell equivalents are conjugated to a hapten.

22. The method of claim 21, in which the immunomodulatory compound is cyclophosphamide.

23. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a composition comprising 2×10^5 to 2.5×10^6 haptenized or non-haptenized autologous tumor cells or tumor cell equivalents free of any adjuvant;

(b) four to seven days after initiation of the treatment, cyclophosphamide; and

(c) at least one week after initiation of the treatment, a composition comprising an adjuvant and from 2×10^5 to about 1×10^7 autologous tumor cells or tumor cell equivalents, wherein said tumor cells or tumor cell equivalents are conjugated to a hapten.

24. The method in claim 23, in which the adjuvant is *Bacille Calmette-Guerin*.

25. The method of claim 21, wherein the composition administered on the first day of treatment comprises haptenized tumor cells or tumor cell equivalents.

26. The method of claim 21, wherein the composition administered on the first day of treatment comprises a mixture of haptenized and non-haptenized tumor cells or tumor cell equivalents.

28. (Revised) The method of claim 21, wherein the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.

29. The method of claim 28, in which the hapten is dinitrophenyl.

30. (Revised) The method of claim 21, wherein the composition administered on the first day of treatment comprises tumor cell equivalents.

32. The method of claim 21, wherein the tumor cells or tumor cell equivalents originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.

33. The method of clam 21, wherein the tumor is melanoma.

34. The method of claim 21, wherein the tumor is ovarian cancer.

35. The method of claim 21, wherein the tumor cells are rendered incapable of growth or multiplication *in vivo* by irradiation.

37. The method of claim 21, wherein the tumor cells of the first composition are rendered incapable of growth or multiplication *in vivo* by haptenization.

38. The method of claim 23, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

39. The method of claim 21, wherein the mammalian patient is a domestic pet or livestock.

40. The method of claim 21, wherein the immunomodulatory agent is administered 5 to 7 days after initiation of the treatment.

41. The method of claim 21, wherein the patient is a human.

42. The method of claim 23, wherein the mammalian patient is a domestic pet or livestock.

43. (Revised) The method of claim 21, wherein the adjuvant is selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

44. The method of claim 23, wherein the patient is a human.

45. The method of claim 23, wherein the cyclophosphamide is administered 5 to 7 days after initiation of the treatment.

46. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a first composition comprising 2×10^5 to about 2.5×10^6 haptenized or non-haptenized tumor cells or tumor cell equivalents free of any adjuvant;

(b) an immunomodulatory agent that inhibits immune suppression; and

(c) at least one additional composition comprising from about 2×10^5 to 1×10^7 tumor cells or tumor cell equivalents, wherein said tumor cell or tumor cell equivalents are conjugated to a hapten.

47. (Revised) The method of claim 23, wherein the hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, N-iodoacetyl-N'-(5-sulfonic 1-naphthyl) ethylene diamine, trinitrobenzenesulfonic acid, fluorescein isothiocyanate, arsenic acid benzene isothiocyanate, sulfanilic acid, arsanilic acid, dinitrobenzene-S-mustard and combinations thereof.

48. The method of claim 23, wherein the tumor is melanoma.

49. The method of claim 23, wherein the tumor is ovarian cancer.

50. (Revised) The method of claim 46, wherein the second composition comprises an adjuvant ~~is~~ selected from the group consisting of *Bacille Calmette-Guerin*, Q-21, and detoxified endotoxin.

55. (Revised) A method for inducing an anti-tumor response in a mammalian patient suffering from a tumor, which method comprises administering to the patient in the following order:

(a) on the first day of treatment, a composition comprising 2×10^5 to 2.5×10^6 haptenized or non-haptenized tumor cells or tumor cell equivalents free of any adjuvant;

(b) four to seven days after initiation of the treatment, cyclophosphamide; and

(c) at least one week after initiation of the treatment, a composition comprising an adjuvant and from 2×10^5 to 1×10^7 tumor cells or tumor cell equivalents, wherein said tumor cells or tumor cell equivalents are conjugated to a hapten.

56. (Revised) The method of claim 55, in which the adjuvant is *Bacille Calmette-Guerin*.

57. (Added) The method of claim 23, wherein the tumor cells or tumor cell equivalents originate from a tumor selected from the group consisting of melanoma, ovarian cancer, colon cancer, breast cancer, rectal cancer, lung cancer, kidney cancer, prostate cancer, and leukemia.